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Signature:  (Quyen Nguyen)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/824,936
Confirmation No.: 7289
Filing Date: April 14, 2004
Inventor(s): Vahid SAADAT et al.
Title: METHOD AND APPARATUS FOR OBTAINING
ENDOLUMINAL ACCESS
Examiner: Matthew J. Kasztejna
Group Art Unit: 3739

APPEAL BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
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Sir:

This is an Appeal Brief for the above-identified application in which pending claims 1, 2, 5-9, 19, 23, 24, 26, 27, 29-33, 36-38, 40-43, and 65-77 were rejected in a Final Office Action mailed March 11, 2010 ("the Office Action").

A Notice of Appeal was filed in this case on August 11, 2010. The fees required for filing this Appeal Brief are transmitted herewith. The Commissioner is authorized to charge **Deposit Account No. 50-3973** for any other fees that may be due with this Appeal, referencing Attorney Docket No. **USGINZ00700**.

TABLE OF CONTENTS

	<u>PAGE</u>
I. REAL PARTY IN INTEREST	3
II. RELATED APPEALS AND INTERFERENCES	4
III. STATUS OF THE CLAIMS	5
IV. STATUS OF AMENDMENTS	6
V. SUMMARY OF CLAIMED SUBJECT MATTER	7
VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL	10
VII. ARGUMENT	11
VIII. CLAIMS APPENDIX	18
IX. EVIDENCE APPENDIX	24
X. RELATED PROCEEDINGS APPENDIX	25

Application No.: 10/824,936
Examiner: Kasztejna, Matthew John

Attorney Docket No.: USGINZ00700

I. REAL PARTY IN INTEREST

The Application is assigned to USGI Medical Inc., a Delaware Corporation having its principal place of business at 1140 Calle Cordillera, San Clemente, California 92673.

II. RELATED APPEALS AND INTERFERENCES

An appeal is currently pending in United States Patent Application Serial No. 11/036,029, which is related to the present application. An appeal brief is being filed in the foregoing case on the same date as the present Appeal Brief.

III. STATUS OF THE CLAIMS

Claims 1, 2, 5-9, 19, 23, 24, 26, 27, 29-33, 36-38, 40-43, and 65-77 were finally rejected and are the subject of this Appeal. Claims 3-4, 10-18, 20-22, 25, 28, 34-35, 39, and 44-64 were cancelled.

Application No.: 10/824,936
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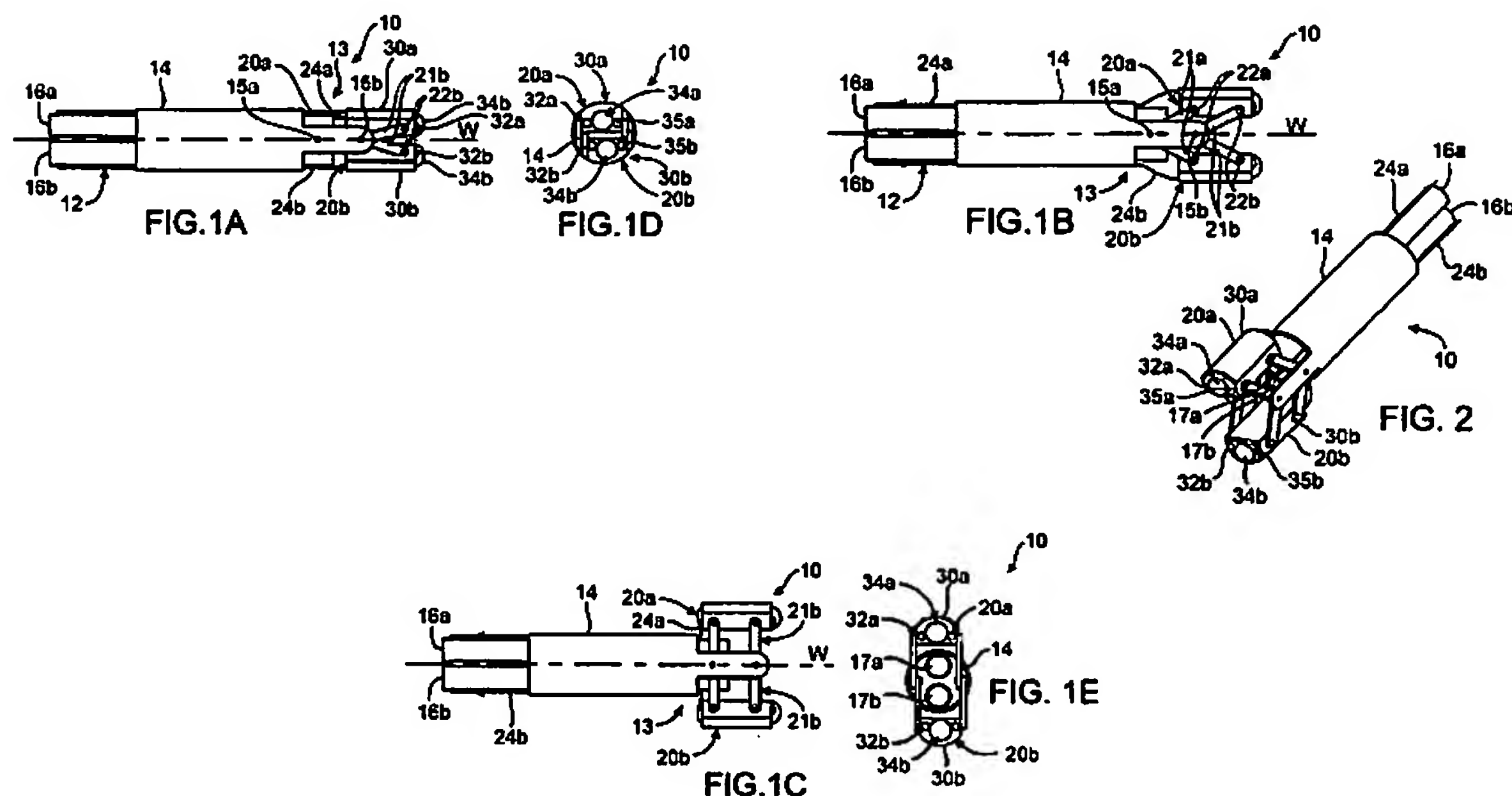
IV. STATUS OF AMENDMENTS

No amendments were filed subsequent to final rejection of the claims.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A summary of independent claims, as well as those dependent claims to which separate arguments are being presented, as required by 37 C.F.R. § 41.37(c)(1)(v), and a non-limiting list of locations where support may be found [bracketed citations] is provided as follows:

The claims on appeal describe apparatus and methods for obtaining endoluminal access into a body lumen, conduit, organ, or passageway of the body of a patient the purpose of, for example, visualizing a target tissue for diagnosis and/or therapy. Exemplary embodiments of the claimed apparatus are set forth in at least Figures 1A-E and 2, which are reproduced below, and is described in the specification at least at paragraphs 0026-36.



Figures 1A-E and 2 show an endoluminal access apparatus 10 that includes an elongate body 12 having a working axis W and a distal region 13. The apparatus includes a housing 14 that may be slidably disposed over one or more working lumens 16a, 16b. One or more articulating elements 20a, 20b may be pivotally coupled to the housing 14 by linkages 21a, 21b, which extend between a first set of hinges 22a, 22b on the articulating elements 20a, 20b and a second set of hinges 15a, 15b on the housing 14.

Turning to the specific claims, **claim 1** describes an apparatus for obtaining endoluminal access. [Paragraph 0025, lines 1-7; FIGS. 1A-E and 2]. The apparatus includes an elongate body configured for insertion within a body lumen, with the elongate body having a working axis and a distal region. [Paragraph 0026, lines 1-3, 6-7; FIGS. 1A-C]. In some embodiments, the elongate body is a multi-segmented and rigidizable, having a flexible state and a rigidized state, as described in co-pending U.S. Patent Application Serial No. 10/797,485. [Paragraph 0026, lines 3-6]. At least two working lumens extend through the elongate body. [Paragraph 0027, lines 1-2; FIGS. 1A-E and 2].

At least one articulating element is pivotally coupled to the housing via at least one linkage that extend between a first hinge located on the articulating element and a second hinge on the housing. [Paragraph 0027, lines 3-5; FIGS. 1A-E and 2]. The articulating element moves from an in-line position in which at least one of the working lumens is substantially covered by the articulating element, to an off-axis position in which the working lumen is not covered by the articulating element. [Paragraphs 0031-32; FIGS. 1A and 1D, 1C and 2].

Claim 31 describes a method for obtaining endoluminal access. [Paragraph 0025, lines 1-7; paragraph 0057; FIGS. 1A-E and 2]. The method includes advancing an elongate body into a body lumen, with the elongate body having an articulatable element disposed near or at its distal region. [Paragraph 0026, lines 1-3, 6-7; paragraph 0027, lines 3-5; FIGS. 1A-E and 2]. The articulating element is moved from a position in-line with or adjacent to a working axis of the elongate body – in which at least one of the working lumens is substantially covered by the articulating element – to a position out of line with working axis. [Paragraphs 0031-32; FIGS. 1A and 1D, 1C and 2]. Once the distal opening of the working lumen is exposed, a diagnostic or therapeutic tool is passed through the working lumen, as the articulating element is maintained in the out-of-line position. [Paragraphs 0031-32; FIGS. 1A and 1D, 1C and 2].

Finally, **claim 65** describes an apparatus for obtaining endoluminal access. [Paragraph 0025, lines 1-7; FIGS. 1A-E and 2]. The apparatus includes a substantially flexible elongate body configured for insertion within a body lumen, with the elongate body having a working axis and a distal region. [Paragraph 0026, lines 1-3, 6-7; FIGS.

1A-C]. At least two working lumens extend through the elongate body. [Paragraph 0027, lines 1-2; FIGS. 1A-E and 2].

At least one articulating element is pivotally coupled to the housing via at least one linkage that extend between a first hinge located on the articulating element and a second hinge on the housing. [Paragraph 0027, lines 3-5; FIGS. 1A-E and 2]. The articulating element moves from an in-line position in which at least one of the working lumens is substantially covered by the articulating element, to an off-axis position in which the working lumen is not covered by the articulating element. [Paragraphs 0031-32; FIGS. 1A and 1D, 1C and 2].

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellants respectfully request the Board of Patent Appeals and Interferences to review the following grounds of rejection on appeal:

1. Whether claims 31-33, 36-38, 40-43, and 65-77 are patentable under 35 U.S.C. § 102(e) over U.S. Patent Application Publication No. 2005/0096502 to Khalili (hereinafter “Khalili”).
2. Whether claims 1-2, 5-9, 19, 23-24, 26-27, and 29-30 are patentable under 35 U.S.C. § 103(a) over Khalili in view of U.S. Patent No. 5,251,611 to Zehel et al. (“Zehel”).

VII. ARGUMENT

Appellants respectfully submit that claims 1, 2, 5-9, 19, 23, 24, 26, 27, 29-33, 36-38, 40-43, and 65-77 are in proper form and are patentable over the prior art of record. Appellants request that the Board overturn the Examiner's final rejection of the claims.

During patent examination, the PTO bears the initial burden of presenting a prima facie case of unpatentability. In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992). The Office has not met the initial burden of demonstrating unpatentability, as will be appreciated by the Board upon review of this Appeal.

A. The Office erred in rejecting claims 31-33, 36-38, 40-43, and 65-77 under 35 U.S.C. § 102(e) because the Khalili Publication does not teach each and every element of Appellants' claimed invention.

Claims 31 and 65 are presented below:

31. A method for obtaining endoluminal access, the method comprising:

advancing an elongate body having at least one articulatable element disposed near or at a distal region thereof into a body lumen;

moving the articulatable element from a position in-line with or adjacent to a working axis of the elongate body to a position out-of-line with the working axis, thereby at least substantially exposing a distal opening of a working lumen provided in the elongate body; and

passing a diagnostic or therapeutic tool through the working lumen while the articulatable element is maintained in the out-of-line position.

65. Apparatus for obtaining endoluminal access, the apparatus comprising:

a substantially flexible elongate body having a working axis and a distal region, the elongate body configured for insertion within a body lumen;

at least two working lumens extending through the elongate body;

at least one articulating element disposed near or at the distal region of the elongate body and pivotally connected to the elongate body near or at its distal region by a linkage member pivotally connected to a first hinge on the articulating element and a second hinge on the elongate body,

wherein the at least one articulating element articulates from an in-line position to an off-axis position relative to the working axis of the elongate body, and wherein a distal opening of at least one of the working lumens is substantially covered by the at least one articulating element in the in-line position and is substantially uncovered by the at least one articulating element in the off-axis position.

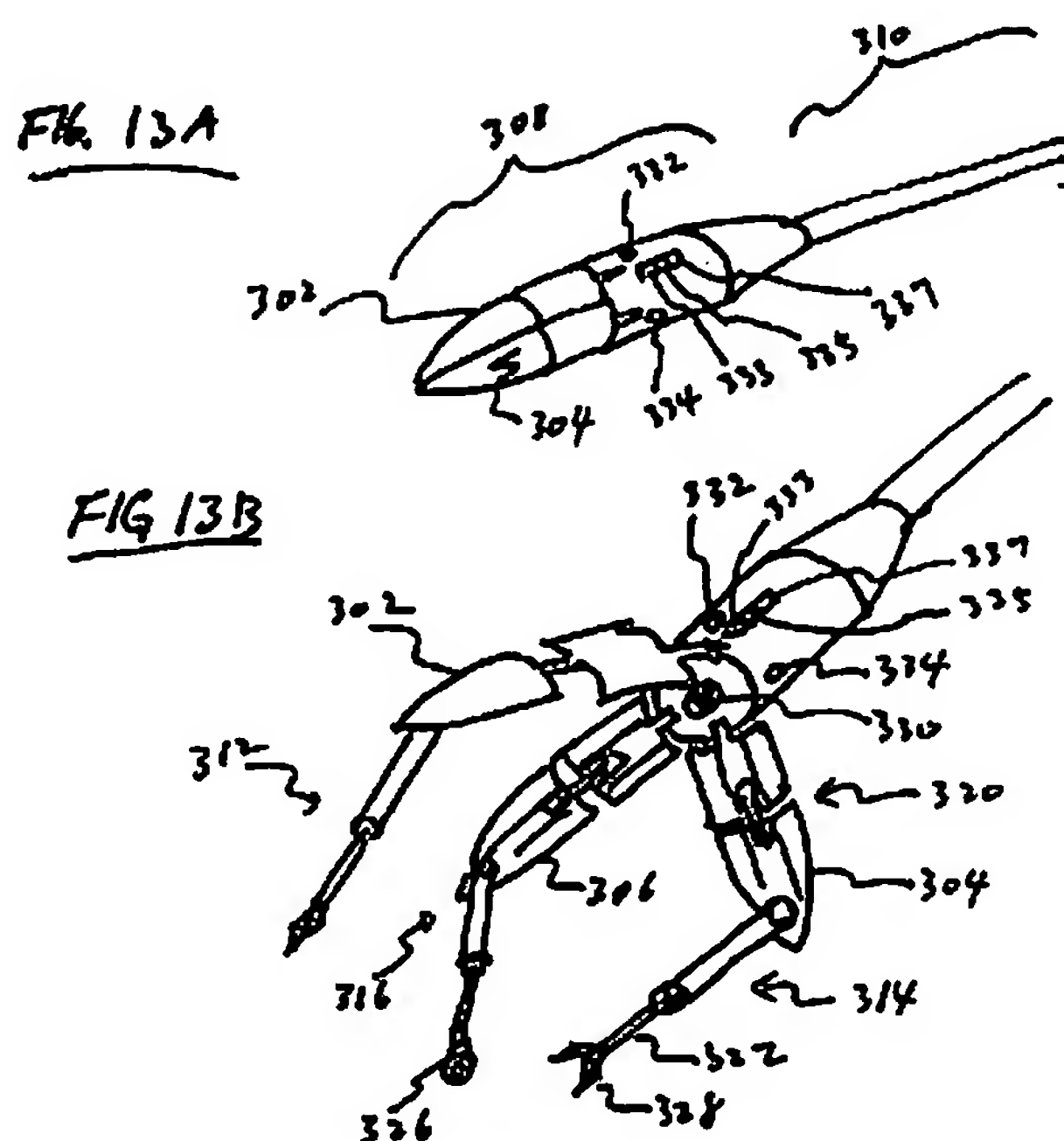
Claim 31 recites a method that includes, *inter alia*, steps of advancing an elongate body having at least one articulatable element disposed at or near a distal region thereof into a body lumen, and the following two additional method steps (emphasis added):

- moving the articulatable element from a position in-line with or adjacent to a working axis of the elongate body to a position out-of-line with the working axis, thereby at least substantially exposing a distal opening of a working lumen provided in the elongate body, and
- passing a diagnostic or therapeutic tool through the working lumen while the articulatable element is maintained in the out-of-line position.

Claim 65 recites an apparatus that includes, *inter alia*, a substantially flexible elongate body, at least one articulating element disposed at or near a distal region of the elongate body, and the following additional limitations (emphasis added):

- at least two working lumens extending through the elongate body; and
- wherein the at least one articulating element articulates from an in-line position to an off-axis position relative to the working axis of the elongate body, and wherein a distal opening of at least one of the working lumens is substantially covered by the at least one articulating element in the in-line position and is substantially uncovered by the at least one articulating element in the off-axis position.

In the rejections of claims 31 and 65, the Office Action (at pp. 3-4) relies upon the FIG. 13A-B embodiment of the Khalili publication, shown below. The Office Action identifies a camera 330 as allegedly corresponding with the “working lumen” recited in claim 31 and with one of the “at least two working lumens” recited claim 65. The Office Action further states that “a distal opening 330 of one of the working lumens is substantially covered by” one of the robotic arms 312-314 in the in-line position and is substantially uncovered by the robotic arms in the off-axis position.



Appellants respectfully disagree with the contention stated in the Office Action that the Khalili camera 330 corresponds with a “working lumen” recited in claims 31 and 65. In particular, Appellants submit that this finding is based upon an unreasonable interpretation of the limitations of claims 31 and 65 identified above. While it is true that claims undergoing examination are to be given their broadest reasonable construction, any such interpretation must be “consistent with the specification” and the claim language must be read “in light of the specification as it would be interpreted by one of ordinary skill in the art.” In re Suitco Surface, Inc., No. 09-1418 (April 14, 2010) (citations omitted). Appellants submit that the constructions of claims 31 and 65 proposed in the Office Action do not satisfy this standard.

The recitation in each of the claims of “a working lumen” or “at least two working lumens” refers to an open space(s), channel(s), or conduit(s) to be used for passage of diagnostic or therapeutic tools therethrough. This interpretation is supported by Appellants’ specification, which consistently uses the terms to refer to such a structure. (See, e.g., ¶ 0002: “The elongate body may also include *a working lumen to facilitate passage of diagnostic or therapeutic tools therethrough*, or for injection of fluids or to draw suction.” See also ¶ 0048: “In FIG. 7, first steerable shaft 82a illustratively is shown with working lumen 86 that extends through the shaft, as well as

through cable 84a and elongate body 72'. Exemplary grasper tool 90 *is shown advanced through lumen 86.*) The claim language itself further supports this interpretation by reciting, in claim 31, a method step of “passing a diagnostic or therapeutic tool through the working lumen while the articulatable element is maintained in the out-of-line position.”

Comparing the embodiment of the Khalili publication relied upon in the Office Action to reject claims 31 and 65, it is clear that the camera 330 does not constitute a “working lumen” as that claim term would be understood by the skilled worker in the context of Appellants’ Specification. It follows that opening the leaflets 312-316 of the Khalili device does not result in “at least substantially exposing a distal opening of a working lumen” as claimed, nor does Khalili teach “passing a diagnostic or therapeutic tool through the working lumen” as also claimed. For these reasons, there can be no anticipation of either of claims 31 or 65 by the Khalili publication.

The Office Action’s “Response to Arguments” section suggests (at pg. 10) that Khalili discloses a “working lumen” which houses the camera 330. There is no support in the Khalili publication for this contention. Moreover, even if a subassembly of the Khalili device included at one time (e.g., during assembly) a conduit or channel that would constitute a “working lumen,” the body of the camera 330 is installed in the conduit or channel, and there is therefore no longer a “working lumen” as claimed. The “Response to Arguments” section also proposes (at pp. 11-12) that “Khalili teaches various other embodiments that also read on claim 31.” Each of the proposed grounds for rejection is flawed – e.g., advancing a robotic tool arm through a port (as per Figs. 5-6 and 7a) does not meet the limitation of “substantially exposing a distal opening of a working lumen” – and none establishes that either of claims 31 or 65 is anticipated by the Khalili publication.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236 (Fed. Cir. 1989). Here, the Office has not met the burden of demonstrating that the Appellants’ claims are anticipated by the Khalili

publication. For at least these reasons, Appellants' claims 31 and 65 are patentable over Khalili. Claims 32-33, 36-38, and 40-43 depend from claim 31 and include the limitations thereof. Claims 66-77 depend from claim 65 and include the limitations thereof. Accordingly, these claims are patentable over Khalili for the same reasons. Therefore, the rejections of claims 31-33, 36-38, 40-43, and 65-77 should be overturned by the Board.

B. The Office erred in rejecting claims 1-2, 5-9, 19, 23-24, 26-27, and 29-30 under 35 U.S.C. § 103(a) because the combination of Khalili and Zehel do not teach each and every element of Appellants' claimed invention.

Claim 1 is presented below:

1. (Currently Amended) Apparatus for obtaining endoluminal access, the apparatus comprising:

an elongate body having a working axis and a distal region, the elongate body configured for insertion within a body lumen and comprising a plurality of links and at least one tensioning wire whereby said elongate body has a first, substantially flexible state and a second, substantially rigid state;

at least two working lumens extending through the elongate body;

at least one articulating element disposed near or at the distal region of the elongate body and pivotally connected to the elongate body near or at its distal region by a linkage member pivotally connected to a first hinge on the articulating element and a second hinge on the elongate body,

wherein the articulating element articulates from an in-line position to an off-axis position relative to the working axis of the elongate body, and wherein a distal opening of at least one of the working lumens is substantially covered by the articulating element in the in-line position and is substantially uncovered by the articulating element in the off-axis position.

Like claim 65, claim 1 recites an apparatus for obtaining endoluminal access that includes, *inter alia*, "at least two working lumens extending through the elongate body," and "wherein a distal opening of at least one of the working lumens is substantially covered by the articulating element in the in-line position and is substantially uncovered by the articulating

element in the off-axis position.” As discussed above, the Khalili publication does not describe or suggest a device that meets these limitations.

The Zehel patent does not correct the above-specified deficiencies of the Khalili publication.

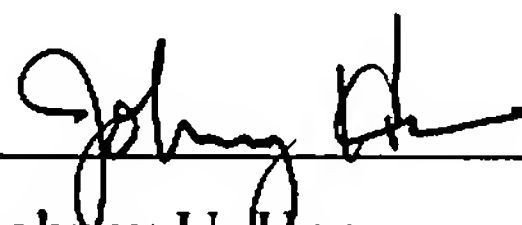
To establish a prima facie case of obviousness under 35 U.S.C § 103(a) in view of a reference or combination of references, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references(s) must teach or suggest all of the claim limitations. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Finally, in determining the differences between the prior art and the claims, the question under 35 U.S.C § 103(a) is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.

Here, the Office has not met the burden of demonstrating that the Appellants’ claims are unpatentable over the combination of Khalili and Zehel. For at least these reasons, Appellants’ claim 1 is patentable over Khalili and Zehel. Claims 2, 5-9, 19, 23-24, 26-27, and 29-30 depend from claim 1 and include the limitations thereof. Accordingly, these claims are patentable over the combination of Khalili and Zehel for the same reasons. Therefore, the rejections of claims 1-2, 5-9, 19, 23-24, 26-27, and 29-30 should be overturned by the Board.

CONCLUSION

For at least the reasons set forth above, the claims currently pending in the application are patentable over the prior art of record, and the rejections of those claims under 35 U.S.C. §§ 102(e) and 103(a) are improper and should be withdrawn. Appellants respectfully request the Board to overturn the Examiner's rejections with instructions to allow the claims.

Respectfully submitted,



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VIII. CLAIMS APPENDIX

1. Apparatus for obtaining endoluminal access, the apparatus comprising:
an elongate body having a working axis and a distal region, the elongate body configured for insertion within a body lumen and comprising a plurality of links and at least one tensioning wire whereby said elongate body has a first, substantially flexible state and a second, substantially rigid state;
at least two working lumens extending through the elongate body;
at least one articulating element disposed near or at the distal region of the elongate body and pivotally connected to the elongate body near or at its distal region by a linkage member pivotally connected to a first hinge on the articulating element and a second hinge on the elongate body,
wherein the articulating element articulates from an in-line position to an off-axis position relative to the working axis of the elongate body, and wherein a distal opening of at least one of the working lumens is substantially covered by the articulating element in the in-line position and is substantially uncovered by the articulating element in the off-axis position.
2. The apparatus of claim 1, wherein the articulating element comprises a visualization element configured to image within a body lumen.
3. - 4. (Cancelled).
5. The apparatus of claim 1, wherein the articulating element further comprises at least two articulating elements.
6. The apparatus of claim 5, wherein the at least two articulating elements are configured for independent off-axis articulation.
7. The apparatus of claim 5, wherein the at least two articulating elements are configured for coordinated off-axis articulation.

8. The apparatus of claim 5, wherein the at least two articulating elements comprise at least two visualization elements configured to provide stereoscopic visualization.

9. The apparatus of claim 8, wherein a focal depth of the at least two visualization elements may be altered by altering a relative angle between the at least two visualization elements.

10-18. (Cancelled).

19. The apparatus of claim 1 further comprising a visualization element and wherein off-axis articulation of the articulating element is configured to expose the visualization element.

20- 22. (Cancelled).

23. The apparatus of claim 1 further comprising a housing configured to couple the articulating element to the elongate body and to facilitate articulation of the articulating element.

24. The apparatus of claim 1 wherein the at least one articulating element is pivotally connected to the elongate body by a pair of pivoting linkage members, with each of the pair of linkage members being pivotally connected to a first hinge on the articulating element and a second hinge on the elongate body.

25. (Cancelled).

26. The apparatus of claim 1, wherein the elongate body is steerable.

27. The apparatus of claim 1, wherein the elongate body is rigidizable.

28. (Cancelled).

29. The apparatus of claim 1, wherein the articulating element further comprises a diagnostic or therapeutic tool.

30. The apparatus of claim 1 further comprising an atraumatic tip.

31. A method for obtaining endoluminal access, the method comprising:

advancing an elongate body having at least one articulatable element disposed near or at a distal region thereof into a body lumen;

moving the articulatable element from a position in-line with or adjacent to a working axis of the elongate body to a position out-of-line with the working axis, thereby at least substantially exposing a distal opening of a working lumen provided in the elongate body; and

passing a diagnostic or therapeutic tool through the working lumen while the articulatable element is maintained in the out-of-line position.

32. The method of claim 31, further comprising imaging within the body lumen with a visualization element disposed within or upon the articulatable element.

33. The method of claim 32, wherein imaging further comprises imaging stereoscopically.

34. - 35. (Cancelled).

36. The method of claim 31 further comprising injecting or withdrawing a fluid through the working lumen.

37. The method of claim 31, wherein articulating the articulatable element further comprises expanding the articulatable element from a reduced delivery

configuration to an expanded deployed configuration, and with the articulatable element in a fixed position relative to the body when the articulatable element is in the expanded deployed configuration.

38. The method of claim 31 further comprising repositioning the articulating element in-line with or adjacent to the working axis of the elongate body, at a position in front of the elongate body.

39. (Cancelled).

40. The method of claim 38 further comprising manipulating the elongate body and re-articulating the articulatable element out-of-line with the working axis.

41. The method of claim 33, further comprising altering a focal depth during stereoscopic imaging.

42. The method of claim 31 further comprising steering the elongate body within the body lumen.

43. The method of claim 31 further comprising rigidizing the elongate body within the body lumen.

44-64. (Cancelled)

65. Apparatus for obtaining endoluminal access, the apparatus comprising:
a substantially flexible elongate body having a working axis and a distal region,
the elongate body configured for insertion within a body lumen;
at least two working lumens extending through the elongate body;
at least one articulating element disposed near or at the distal region of the
elongate body and pivotally connected to the elongate body near or at its distal region by

a linkage member pivotally connected to a first hinge on the articulating element and a second hinge on the elongate body,

wherein the at least one articulating element articulates from an in-line position to an off-axis position relative to the working axis of the elongate body, and wherein a distal opening of at least one of the working lumens is substantially covered by the at least one articulating element in the in-line position and is substantially uncovered by the at least one articulating element in the off-axis position.

66. The apparatus of claim 65, wherein the at least one articulating element comprises a visualization element configured to image within a body lumen.

67. The apparatus of claim 65, wherein the at least one articulating element comprises at least two articulating elements.

68. The apparatus of claim 67, wherein the at least two articulating elements are configured for independent off-axis articulation.

69. The apparatus of claim 67, wherein the at least two articulating elements are configured for coordinated off-axis articulation.

70. The apparatus of claim 67, wherein the at least two articulating elements comprise at least two visualization elements configured to provide stereoscopic visualization.

71. The apparatus of claim 70, wherein a focal depth of the at least two visualization elements may be altered by altering a relative angle between the at least two visualization elements.

72. The apparatus of claim 65 further comprising a visualization element that is substantially covered by the at least one articulating element in the in-line position and is substantially uncovered by the at least one articulating element in the off-axis position

73. The apparatus of claim 65 wherein the at least one articulating element is pivotally connected to the elongate body by a pair of pivoting linkage members, with each of the pair of linkage members being pivotally connected to a first hinge on the at least one articulating element and a second hinge on the elongate body.

74. The apparatus of claim 65, wherein the elongate body is steerable.

75. The apparatus of claim 65, wherein the elongate body is rigidizable.

76. The apparatus of claim 65, wherein the at least one articulating element further comprises a diagnostic or therapeutic tool.

77. The apparatus of claim 65 further comprising an atraumatic tip.

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Examiner: Kasztejna, Matthew John

Attorney Docket No.: USGINZ00700

IX. EVIDENCE APPENDIX

None.

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X. RELATED PROCEEDINGS APPENDIX

None.